IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Declaration under 37 CFR 1.131 of Howard A. MacCord, Jr.

Howard A. MacCord, Jr. does hereby say as follows:

1. I am one of the attorneys of record in this application and have been personally handling the preparation and prosecution of this application since its inception. During the year 2000, I was assisted by my associate at the time, Craig H. Popalis, whose registration number is 49,028.

2. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before September 5, 2000, and applicants were diligent to a constructive redirection to practice from a time prior to September 5, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to September 5, 2000:

a. applicants disclosed the invention to me on a date before September 5, 2000, in a document attached as Exhibit B.

b. based upon that written disclosure and a supplemental oral disclosure from the inventors, counsel prepared an outline of the invention before September 5, 2000, set forth in a document attached as Exhibit C.

3. In preparing this declaration, I have consulted stored electronic records of the time entries for the work by Mr. Popalis and me in connection with the preparation of this application as well as stored indicia concerning accesses to electronic versions of the documents attached as Exhibits B and C. The following statements are made based on those stored electronic records:

a. The document attached as Exhibit B was reviewed by either Mr. Popalis or me on August 11 and 29, 2000, and again on September 5, 15, and 19, 2000.

b. The document attached as Exhibit C was reviewed by either Mr. Popalis or me on August 29, September 5, 15, and 19, 2000, and October 24, 2000.

c. On 8/9/2000, Craig H. Popalis began work on the preparation of a patentability opinion, accessing drafts of it on September 15, 18, 20 and 25, 2000, when the opinion was sent to the client.

d. On 10/17/2000, Howard A. MacCord, Jr. began work on preparing the patent application.

e. On 10/23/2000, Mr. Popalis spent time Drafting claims.

f. On 10/25/2000, Mr. Popalis spent time drafting the application.

g. On 10/26/2000, Mr. MacCord worked on preparing the application.

h. On 10/26/2000, Mr. Popalis spent time drafting the application.

i. On 10/27/2000, Mr. Popalis spent time drafting the specification.

j. On 10/30/2000, Mr. Popalis spent time drafting the specification.

k. On 10/31/2000, Mr. Popalis spent time drafting the specification.

l. On 11/2/2000, Mr. MacCord reviewed and revised Mr. Popalis's draft application.

m. On 11/2/2000, Mr. Popalis revised the application.

n. On 11/7/2000, Mr. MacCord reviewed the draft application.

o. On 11/7/2000, Mr. Popalis revised the application.

p. On 11/10/2000, Mr. Popalis made a final version of the application and a copy of it was sent to the client; a copy of this draft of the application for the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES was submitted with the Declarations of the inventors in June 2004, as Exhibit A.

q. On 11/20/2000, Mr. MacCord reviewed the application again.

r. a final draft with formal documents for signature was forwarded by counsel to the inventors on December 5, 2000.

s. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

t. On 12/13/2000, Mr. Popalis prepared the Final documentation for filing application.

u. On 12/14/2000, Mr. MacCord reviewed the final application for filing, which took place on December 14, 2000.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Howard A. MacCord, Jr.,
Reg. No. 28,639

18 July 2011
Date

I. A) Collects info "On site"

1) Form template broadcasted to collection site or downloads to site via Internet, a disk or networked.

2) RFID Label with accessioning number is referenced to form through RF reader or Barcode at collection site.

3) Specimen is labeled with RFID Label or Barcode referenced to RFID label to be shipped to lab.

4) Form is completed by collection site and if necessary patient signature is acquired through elective signature software.

5) Form is then transmitted to laboratory.

Lab Receiving and Electronic Paperwork matches

1) When specimen is received, a RF reader reads it automatically. This process matches sample with paperwork and closes loop between paperwork and specimen.
2) Routing of specimen can be done at point of receipt.

Advantages of System

1) No test request forms
2) Automatic real time inventory system
3) Rerouting of specimen
4) Increased hours available to do testing by decreasing receiving time required
5) Lab can preplan work because they know what is arriving before hand
6) Less error rate
7) Fewer employees needed-no input personnel
8) Improves courier system

E&B

OUTLINE OF PAPERLESS CHAIN OF CUSTODY PROCESS
Based upon Discussions with Client on 8/11/00

1. Manufacturer puts bar code and correlated smart label data into database

   Higher initial cost for smart labels

2. Shipper labels included as part of kit shipment to collection site and increment inventory by number of units shipped to correlate by reference number

3. Provide specimen collection containers with correlated bar code and smart label to specimen collection site.
   a. May use EMID labels for toxicology specimens in lieu of RFID
   b. Use RFID for clinical trial specimens

4. Collection site interrogates specimen donor for donor information/data.

5. Collection site collects specimen from donor in collection container having bar code/smart label; enters data into local database with pre-programmed data template.
   a. Use handheld device? (unclear how used?)
   b. Use bar code scanner to correlate specimen with recorded data – automatically correlates specimen with smart label identity in D/B?
   c. Required data fields defined by computer software template
   d. Obtain donor's electronic signature for toxicology (urinalysis) specimens – use of electronic pen/pad
   e. Data tampering after signature voids signature

6. Collection site transmits collected data for specimen to lab via internet.

   Additional step for collection site

7. Lab increments collection site's inventory count by number of samples shipped.

   Planning benefit for lab

8. Lab collects data in specimen data base.

9. Lab processes collected data
   a. Define list of specimens in queue for delivery and testing.
   b. Define list of specimens in queue for gathering from collection sites; define route for courier to collect specimens from multiple collection sites.

   Planning/logistics advantages for lab

10. Courier gathers specimens with smart labels from collection sites and delivers to lab

11. Lab receives specimens from courier.

12. Lab scans incoming specimens using RF/EMID reader
    a. scan all specimens simultaneously ; or as worker with RF nametag handles and inspects, that worker's unique ID number is read and input with RF from sample; worker need not identify himself into database – merely inspect and push OK button
    b. Reads identity information from smart label
    c. Computer correlates incoming specimens with specimen data in D/B
    d. For toxicology specimens w/ EMID, detect tampering

Reduced manpower for receiving process @ lab. Quicker through put for lab receiving section; Use expensive testing machine earlier in day to maximize usage and reduce per- test cost

13. Lab processes data
    a. Ascertains quantities of specimens in queue for specific testing - useful for scheduling and testing machine loading
    b. Data base updated regarding status of specimen
    c. Lab can prioritize specimens for testing as required

Planning and logistics advantages for lab

14. Computer routes specimen to correct testing station/equipment – additional intermediate scanning of RF chip as required for quality control and internal tracking?

QC advantages for lab; faster & more reliable reading than bar code scanning on curved vial

15. Automated material handling equipment directs specimen to correct testing station/machine.

Improvement over prior art?

16. Quality control scan of specimen immediately prior to testing

QC advantages

17. Automated testing performed on specimen

Improvement? Automatic?

18. Testing results recorded electronically on specimen D/B

Improvement? Automatic?

19. Testing results reported to collection site electronically via internet
    a. Also automated written report may be generated as required and sent to collection site

Improvement? Automatic?